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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,710	10/22/2003	Scott H. Gillis	14072-024001 / W 602	9757

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EXAMINER	
PAK, JOHN D	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,710	GILLIS ET AL.	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *103-138* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *103-138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/05,3/05,10/04,8/04,5/04,3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 103-138 are pending in this application.

Claim 130 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Independent claim 103 requires contacting a subject's oral or nasal cavity. Dependent claim 130 recites administering a suppository. Since a lozenge is already recited in claim 130, it appears that the suppository may not be an oral suppository. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 103-138 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating existing respiratory conditions of microbial etiology (e.g. sinusitis with colloidal silver; bacterial/microbial, fungal, viral respiratory condition with antimicrobial, atomically disordered nanocrystalline silver-, gold-, platinum-containing compounds) in a subject, does not reasonably provide enablement for the full scope of "prophylactically treating" all respiratory conditions. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Examiner interprets "prophylactically treating" to include "preventing." Applicant defines "prophylactically treating" as involving "reducing the likelihood that the condition will occur in a subject" (specification page 1, lines 18-20). Such definition necessarily encompasses preventing a condition, as evidenced by specification page 13, line 24. Prevention includes the scope wherein contracting "the condition" is made impossible[1].

The scope of applicant's subjects is extremely broad. Specification page 9 discloses human, dog, cat, horse, reptile, amphibian, fish, turtle, rodent, cow, chicken, turkey, ostrich, sheep.

The scope of applicant's prophylactically treating a condition is extremely broad. The prophylactically treatable or treated condition is open to virtually any etiology, including biofilm, microbial, bacterial, fungal, viral, autoimmune, idiopathic, cancer, hyperproliferation, MMP, inflammation, allergens (specification page 8, lines 16-18 & 26-27; paragraph bridging specification pages 10-11). Disclosed respiratory conditions include asthma, emphysema, bronchitis, pulmonary edema, acute respiratory distress syndrome, bronchopulmonary dysplasia, fibrotic condition such as pulmonary fibrosis, pulmonary atelectasis, tuberculosis, pneumonia, sinusitis, allergic rhinitis, pharyngitis,

[1] See definition of "prevent" in Webster's New World Dictionary, 2nd college edition, page 1127 (1972).

mucositis, stomatitis, chronic obstructive pulmonary disease, bronchiectasis, lupus pneumonitis and cystic fibrosis (paragraph bridging specification pages 10-11).

The state of the prior art or even current state of the art is such that preventing, reducing the likelihood, and treating all such different conditions have not yet been realized with any drug or drugs, let alone with the same drug or drug types. **Medline abstract 2004022628** discloses gold salts to have glucocorticoid-sparing effect[2] in severe asthma but lung function is not improved and not all patients respond. Hepatic dysfunction and interstitial pneumonitis are disclosed as some of the unwanted effects. This reference discloses that "response cannot be predicted a priori," "high incidence of unwanted effects makes it difficult to assess overall benefit/risk ratios," "there is increased risk of opportunistic infection and (theoretically) neoplasia," and "there is lack of knowledge about the long-term effects, beneficial or otherwise, of therapy." **Medline 2002014225** discloses gold compounds as immunosuppressive agents, which have benefits in the treatment of a number of inflammatory disorders. However, it is disclosed that use of gold for asthma cannot be recommended. **Medline abstract 97235909** discloses interstitial pneumonia in the course of gold therapy for rheumatoid arthritis. **Morgan** discloses idiopathic interstitial pneumonia as an incurable, deadly lung disorder (first paragraph). Morgan further discloses that no treatment currently

[2] Glucocorticoids are thought to ameliorate asthma at least partly through T cell inhibition (see cited Medline abstract).

exists for idiopathic interstitial pneumonia and other forms of pulmonary fibrosis (fourth paragraph). Genetic etiology is attributed (third paragraph).

American Lung Association fact sheet for bronchiectasis discloses that bronchiectasis can occur as part of a birth defect, such as in cystic fibrosis. **MedlinePlus** discloses that bronchiectasis can occur as a complication from infection or from inhaling a foreign object.

HCAPLUS abstract 1962:56564 discloses that introduction of silver nitrate into the pulmonary arterial circuit causes pulmonary edema. **HCAPLUS abstract 1961:60892** similarly discloses silver nitrate to provoke pulmonary edema.

As evidenced above, the level of unpredictability in the art is quite high. However, the amount of direction provided by the instant specification is quite lacking. The specification merely provides a laundry list of metal compounds and conditions to be prophylactically treated. There is not one single piece of objective evidence related to prophylactically treating a respiratory condition, as claimed. Specification Examples III-XX and XXVI-XXVIII state prophetic examples of providing various forms of "antimicrobial, atomically disordered, nanocrystalline-silver containing material" to a human subject who does not have nosocomial pneumonia or ventilator associated pneumonia. Specification Examples XXIX-XXXI state prophetic examples of intubating an unspecified adult male animal to treat an unspecified respiratory condition. No objective evidence or result of prevention or treatment is disclosed.

Given the scope of widely divergent respiratory conditions that are readable on the claims, many of which are untreatable and/or unpreventable, and many of which have widely varying etiologies such as genetic or inhalation of foreign particles, the quantity of experimentation needed to use the invention to the full extent claimed, based on the content of the disclosure, would be serious and undue. Based on the totality of the above discussed factors, one skilled in the art would be faced with undue experimentation in order to practice the instant invention to the full extent claimed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 103-104, 106-107, 109, 111, 115, 116, 119-121, 124, 125-127, 129-131, 133, 136-138 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/60999 (hereinafter WO '999).

WO '999 discloses application of agents with anti-inflammatory, antiseptic properties to the lower respiratory tract to treat infections[3] (page 1, lines 6-12; claim 22). Treatment of bronchitis, pneumonia and tuberculosis is disclosed (claim 43). Silver compound as the antiseptic agent is disclosed (page 5, line 7; claim 27). Liposome, microsphere, nanoparticle particulate carriers are disclosed for application to the lower respiratory tract (page 5, lines 17-21). Administration by nebulization agent loaded with particulates, aerosol or dry powder inhalation is disclosed (page 6, line 22 to page 7, line 14; claims 38, 39, 41).

It is the Examiner's position that the dry powder inhalation or aerosol inhalation taught by WO '999 meets applicant's claimed feature of contacting a first area to reduce the occurrence of the condition at a second area. For example, treating pneumonia (WO '999, claim 43) by inhaling an aerosol necessarily contacts the oral or nasal cavity and then subsequently contacts other areas of the respiratory system. Treating a subject with pneumonia necessarily involves recognition of 100% possibility of occurrence of pneumonia in the lower respiratory tract of the subject. A silver compound must comprise atoms. As for the "prophylactic ratio" in applicant's claim 133, it is the Examiner's position that since the same substance is administered to the same patient via the same delivery protocol, the same result would necessarily be obtained. The claims are thereby anticipated.

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[3] The Examiner is not relying on "preventing" infections disclosure in this reference, e.g. claim 22 and

Claims 103-104, 106-107, 109-111116, 119, 121, 124, 127, 129, 131, 133, 136 are rejected under 35 U.S.C. 102(b) as being anticipated by Derwent abstract 1994-089981.

Derwent abstract 1994-089981 discloses the use of activated electrolytic silver water in the inhalatory treatment of tuberculosis.

It is the Examiner's position that the inhalation of the electrolyzed silver water solution taught by the cited reference meets applicant's claimed feature of contacting a first area to reduce the occurrence of the condition at a second area. Inhaling contacts the oral or nasal cavity and then subsequently contacts other areas of the respiratory system. Inhaling the solution necessarily encompasses a spray. Treating a subject with tuberculosis necessarily involves recognition of 100% possibility of occurrence of tuberculosis in an area that is not the mouth or nose. Electrolyzed silver water comprises ionic species and certainly includes atoms. As for the "prophylactic ratio" in applicant's claim 133, it is the Examiner's position that since the same substance is administered to the same patient via the same delivery protocol, the same result would necessarily be obtained. The claims are thereby anticipated.

Claims 103-104, 106-107, 109, 111, 116, 121, 124, 131, 133-134, 136 are rejected under 35 U.S.C. 102(e) as being anticipated by Quillin (US 6,899,903).

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page 1, line 11.

At the outset, it is noted that Quillin claims benefit of provisional application 60/391,022, filed on 6/25/2002. Disclosure made in the provisional application renders Quillin prior art under 35 USC 102(e).

Quillin discloses treating sinusitis with a solution that contains, inter alia, water and colloidal silver (see columns 5-6 and claim 1; see also provisional application page 1, paragraph 1). The solution is sprayed into the nasal cavity (claim 1; see provisional application, page 1, last paragraph). Treating the sinus with intranasal spray necessarily involves contacting a first area (nasal cavity) to treat a second area (sinuses), where there is recognition of the 100% possibility of sinusitis in said second area. As for the "prophylactic ratio" in applicant's claim 133, it is the Examiner's position that since the same substance is administered to the same patient via the same delivery protocol, the same result would necessarily be obtained.

The claims are thereby anticipated.

Claims 103-104, 106, 109, 111, 116-124, 127-129, 131, 133-134, 136, 138 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Frank (US 6,454,754).

Frank discloses delivering 20-60 ppm colloidal silver suspension via nebulizer, aerosol or spray atomizer to combat infections of the lungs such as bronchitis, chest colds, tuberculosis and sinus infection (claims 1, 4; and column 3, lines 23-55). It is noted that 20 ppm and 60 ppm are 0.002 w/w% and 0.006 w/w%, respectively.

Inhalation through the nose is disclosed to overcome severe sinus infections (column 3, lines 52-55).

It is the Examiner's position that Frank's delivery protocol meets applicant's claimed feature of contacting a first area to reduce the occurrence of the condition at a second area. Nasal inhalation to treat sinus infection is disclosed; and further, delivery via nebulizer, aerosol or spray atomizer necessarily contacts multiple areas before reaching the end target area. Treating a subject with sinus infection, bronchitis or tuberculosis necessarily involves recognition of 100% possibility of occurrence of such conditions in the subject. A silver compound must comprise atoms. As for the "prophylactic ratio" in applicant's claim 133, it is the Examiner's position that since the same substance is administered to the same patient via the same delivery protocol, the same result would necessarily be obtained. The claims are thereby anticipated.

Claims 103-104, 106-114, 116-127, 129, 131, 133-134, 136, 138 are rejected under 35 U.S.C. 102(e) as being anticipated by Burrell et al. (US 7,087,249).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Burrell et al. claim a method of reducing inflammation or infection of a mucosal membrane, including nasal, pulmonary, trachea and pharynx airways (claims 1 and 3-4). The inflamed or infected area is contacted with a therapeutically effective amount of antimicrobial metals in nanocrystalline form, which is characterized by sufficient atomic disorder so that the metal, in contact with an alcohol or water-based electrolyte, releases atoms, ions, molecules or clusters of the metal on a sustainable basis (claim 1). Delivery in the form of a powder, aerosol, spray, mist to the oral cavity or to an area of the nasal, bronchial, pulmonary, trachea or pharynx airways to treat a respiratory disorder is claimed (claims 8-11). 40-500 µg/ml concentration is claimed, which is equivalent to 0.4 w/v% for 40 µg/ml (see claim 9).

Contacting a first area to reduce the occurrence of the condition at a second area is clearly encompassed by Burrell's claims. Burrell's delivery of a powder or aerosol via the oral cavity or nasal airways (claims 8-11) would plainly meet this feature when treating a respiratory disorder. Treating inflammation or infection of pulmonary airways would necessarily entail recognition of 100% possibility of occurrence of the inflammation or infection at an area different from the oral or nasal airways. As for the "prophylactic ratio" in applicant's claim 133, it is the Examiner's position that since the

same substance is administered to the same patient via the same delivery protocol, the same result would necessarily be obtained. The claims are thereby anticipated.

Claims 103-104, 106-115, 121-128, 131-135, 138 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,989,157. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The patent claims are directed to treating a human or animal subject having a bacterial, microbial, fungal or viral respiratory condition by administering a free-standing powder of antimicrobial nanocrystalline metal-containing compound, wherein the metal is silver, gold, platinum or palladium. See claims 1-20. Treatment of bronchitis, tuberculosis, pneumonia, sinusitis, and pharyngitis is claimed (claims 8, 14-19).

The rejected claims read on such conditions and metal-containing compounds. Rejected claim 106 is evidence that the instant claims read on treating subjects that already have the condition. Although the patented claims do not specifically recite "first area" and "second area," inhalation of a free-standing powder to treat respiratory conditions such as bronchitis, tuberculosis, pneumonia, sinusitis, and pharyngitis would necessarily involve contacting a first area to reduce the occurrence of the condition at a second area. Concentration of the metal-containing compound and pharmaceutically acceptable carriers would have been within the skill of the ordinary skilled artisan given

the therapeutic disclosure of the patented claims. Nosocomial pneumonia and ventilator-associated pneumonia are not specifically recited in the patented claims, but such forms of pneumonia are encompassed and fairly suggested by the broadly recited "pneumonia" in patented claims 8 and 17. Aerosol formulation is not specifically recited in the patented claims, but inhaling the dry powder and use of a dry powder inhaler device is claimed (claims 1 and 9), and such claimed disclosure is fairly suggestive of powder aerosol formulation.

For these reasons, the claimed invention would have been recognized by the ordinary skilled artisan in this field as an obvious variation of the invention set forth in the patented claims.

All claims are rejected. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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